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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,832	12/05/2003	William W. Alston	0136.00	8541

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EXAMINER	
ALI, SHUMAYA B	
ART UNIT	**PAPER NUMBER**
3743	

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/729,832	ALSTON ET AL.	
	Examiner	Art Unit	
	Shumaya B. Ali	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-16 and 18-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *6 and 17* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *detailed action*.

DETAILED ACTION

Election/Restrictions

1. Claims 1-5,7-16,18-35 are generic to a plurality of disclosed patentably distinct species comprising: figures 2AB, figures4AB, figures 5A-C, figures 6A-C, figures 7AB, figures 8AB, figures 9AB, and figures 10AB. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

2. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. During a telephone conversation with Tucker Guy on Monday April 18, 2005 a provisional election was made without traverse to prosecute the invention of Figures 2AB, claims 1-5,7-16, 18-35. Affirmation of this election must be made by applicant in replying to this Office action. Claims 6 and 17 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5,7-16,18-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohki et al. US Patent 5,921,236 in view of Chiprich et al. US Patent 5,614,217

5. **As to claim 1, Ohki et al. disclose** an aerosolization system comprising: an aerosolization device **(see fig.2 reference object 1)** comprising a chamber **(see fig.2 reference object 12)** adapted to **(see col.2 lines 29-31)** receive a receptacle **(see fig.4 reference object K)**; and a receptacle containing a pharmaceutical formulation **(receptacle is a capsule, see col.2 line 30-31, it is obviously well know in the art that a capsule inherently contain powder-like medicine of some pharmaceutical formulation)**, the receptacle comprising a wall **(a outer shell of the capsule) where a force is applied (via pump means, see col.2 lines 35-39) to release (via the action of a first and second perforating means) the pharmaceutical content of the capsule (see col.2 lines 39-44), however do not disclose** the wall having a weakened portion that opens when a force is applied, whereby an opening into the receptacle may be created at the weakened portion before, during, or after insertion of the receptacle into the chamber by applying a force to the receptacle. **As to claim 1, Chiprich et al. teach a capsule which is brittle so that it can be broken using finger pressure (see col.2 lines 13-14). Also teach a breakable capsule with a single (see fig.2) or multiple (see fig.3) score line to provide a focal point for applying pressure to the capsule so that it may be readily broken for release of its contents (see col.4 lines 1-6). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the capsule of Ohki in order to provide a brittle capsule with score lines creating weakened portions to the capsule as taught by Chiprich for the purposes of creating a focal point at the weakened portion where a pressure would be applied to break and release the powder contents enclosed in the capsule.**

6. **As to claim 2, Ohki et al. do not disclose** a system according to claim 1 wherein the weakened portion comprises a region of the wall altered so as to fracture at a force less than would be necessary without the alteration. **As to claim 2, Chiprich et al. teach a capsule with multiple score lines (see fig.3, seems to depict spaced apart score lines, therefore the capsule wall is considered to have altered regions of weakened portion at the score lines, see also col.4 lines 5-6) that help to both control the breaking point and to reduce the pressure needed to induce breakage of the capsule to release the fill material contained therein (see col.3 lines 58-63). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the capsule of Ohki in view of Chiprich in order to provide a region of the wall comprising altered weakened portion for the purposes of reducing the pressure needed to induce breakage of the capsule to release the fill material contained therein.**

7. **As to claim 3, Ohki et al. disclose** a system according to claim 1 wherein a portion of the wall having a reduced thickness **(capsule inherently has two ends which are reduced in thickness), however do not disclose** the weakened portion comprises a scored region. **As to claim 3, Chiprich et al. teach a capsule which is brittle so that it can be broken using finger pressure (see col.2 lines 13-14). Also teach a breakable capsule with a single (see fig.2) or multiple (see fig.3) score line to provide a focal point for applying pressure to the capsule so that it may be readily broken for release of its contents (see col.4 lines 1-6). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the capsule of Ohki in order to provide a brittle capsule with score lines creating weakened portions to the capsule as taught by Chiprich for the purposes of creating a focal point at the weakened portion where a pressure would be applied to break and release the powder contents enclosed in the capsule.**

8. **As to claim 4, Ohki et al. disclose** a system according to claim 1 wherein the aerosolization device comprises a force-applying member **(see fig.2 reference object 15)** to apply a force to the weakened portion to create the opening in the receptacle.

9. **As to claim 5, Ohki et al. disclose** a system according to claim 4 wherein the force-applying member comprises a moveable portion **(see fig.2 reference object 8)** of the chamber.

10. **As to claim 7, Ohki et al. disclose** a system according to claim 4 wherein the force-applying member comprises an opening mechanism **(see fig.2 reference object 27)** slidably moveable **(the opening member is part of the movable member, therefore the opening member is considered movable as well, see col.9 lines 56-60)** within the chamber.

11. **As to claim 8, Ohki et al. do not disclose** a system according to claim 7 wherein the opening mechanism comprises an opening member having a blunt tip. **A close review of the applicant's disclosure reveals that the applicant has not established criticalities regarding a particular tip used with the opening member. Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to provide an opening member having either a blunt tip or an inclined cut needle tip as disclosed by Ohki where both tips are capable of perforating a capsule.**

12. **As to claim 9, Ohki et al. disclose** a system according to claim 1 wherein the receptacle comprises a capsule **(see col.2 lines 30-31).**

13. **As to claim 10, Ohki et al. do not disclose** a system according to claim 9 wherein the capsule comprises a wall comprising one or more of gelatin, hydroxypropyl methylcellulose, polyethyleneglycol-compounded hydroxypropyl methylcellulose, hydroxyproplycellulose, and agar. **As to claim 10, Chiprich et al. teach capsule wall composition of gelatin and cellulose/starch contents (see col.2 lines 55-68 and col.3 lines 1-18) providing a vehicle for dispensing pre-measured medicaments (see col.3 lines**

29-30). Also teach the biodegradable nature of the gelatin capsule provides for consumer acceptance of disposable products. Since the capsules as taught by Chiprich contain a non-hygroscopic plasticizer, they require less moisture resistance in their packaging than traditional soft gelatin capsules and therefore provide cost efficiency because of less expensive packaging materials being required (see col.3 lines 38-45). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to add gelatin and cellulose contents to the wall of Ohki in view of Chiprich for the purposes of creating a medicine dispensing vehicle that requires less moisture resistance in their packaging than traditional soft gelatin capsules, therefore further providing cost efficiency because of less expensive packing materials.

14. **As to claim 11, Ohki et al. disclose** system according to claim 1 wherein the receptacle contains a powder pharmaceutical formulation **(see col.2 lines 30-31)**.

15. **As to claim 12, Ohki et al. do not disclose** a system according to claim 11 wherein the powder pharmaceutical formulation comprises particles having a mass median diameter less than 10 gm. **A close review of the applicant's discloser reveals "a particle size selected to permit penetration into the alveoli of the lungs" (see specification page 18, lines 14-15). The mass median diameter will vary depending on the releasing site/the type of tissue absorbing that medication. Mass median diameter can be made smaller or larger to respectively increase or decrease the absorbent nature of the tissue. The medicine administering device disclosed by Ohki is a powder-state medicine filled in a capsule can be employed for a patient with asthma (see col.1 lines 11-13). Therefore, it would have been obvious to one of ordinary skills in the art while preparing the pharmaceutical formulation particles for an asthma patient with a mass median diameter smaller for the purposes**

of increasing the absorbent efficiency of the lung tissue to rapidly reduce possible breathing difficulties experienced by an asthma patient.

16. **As to claim 13, Ohki et al. do not disclose** a system according to claim 11 wherein the powder pharmaceutical formulation has moisture content below 5% by weight. **A close review of the disclosure reveals that the applicant prefers a moisture content below about 10% by weight, usually below about 5% by weight, and preferably below about 3% by weight, also discloses such powder are described in the prior art (see specification page 18, lines 21-25). A range of moisture content (below 10%-below about 3%) presented by the applicant is recognized, however the applicant has not established criticalities between a moisture content of 10% or 3% by weight. As to claim 13, Chiprich et al. teach, a brittle gelatin capsule comprises about 5-15% water by weight. Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the capsule of Ohki in view of Chiprich in order to provide a moisture content of 5-15% since it is well known in the art that a low water content is advantageously used in the process of making a powder-like medicine for the purposes of increasing the drying process of the powder.**

17. **As to claim 27, Ohki et al. disclose** a receptacle **(see fig.4 reference object K)** for use in an aerosolization device **(see fig.2 reference object 1)** comprising a chamber **(see fig.2 reference object 12)** adapted to **(see col.2 lines 29-31)** receive the receptacle, the receptacle comprising: a wall **(a outer shell of the capsule), however do not disclose** having a weakened portion that opens when a force is applied; and a pharmaceutical formulation **(receptacle is a capsule, see col.2 line 30-31, it is obviously well know in the art that a capsule inherently contain powder-like medicine of some pharmaceutical formulation)** within the wall, whereby an opening **(opening is created by a opening member 27, see fig.2),** may be created at the weakened portion before, during, or after insertion of the receptacle into the

chamber by applying a force to the receptacle. **As to claim 27, Chiprich et al. teach a capsule which is brittle so that it can be broken using finger pressure (see col.2 lines 13-14). Also teach a breakable capsule with a single (see fig.2) or multiple (see fig.3) score line to provide a focal point for applying pressure to the capsule so that it may be readily broken for release of its contents (see col.4 lines 1-6). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the capsule of Ohki in order to provide a brittle capsule with score lines creating weakened portions to the capsule as taught by Chiprich for the purposes of creating a focal point at the weakened portion where a pressure would be applied to break and release the powder contents enclosed in the capsule.**

18. **As to claim 28, Ohki et al. do not disclose** a receptacle according to claim 27 wherein the weakened portion comprises a region of the wall altered so as to fracture at a force less than would be necessary without the alteration. **As to claim 28, Chiprich et al. teach a capsule with multiple score lines (see fig.3, seems to depict spaced apart score lines, therefore the capsule wall is considered to have altered regions of weakened portion at the score lines, see also col.4 lines 5-6) that help to both control the breaking point and to reduce the pressure needed to induce breakage of the capsule to release the fill material contained therein (see col.3 lines 58-63). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the capsule of Ohki in view of Chiprich in order to provide a region of the wall comprising altered weakened portion for the purposes of reducing the pressure needed to induce breakage of the capsule to release the fill material contained therein.**

19. **As to claim 29, Ohki et al. disclose** a receptacle according to claim 27 wherein the weakened portion comprises a scored region and/or a portion of the wall having a reduced thickness **(capsule**

inherently has two ends which are reduced in thickness), however do not disclose the weakened portion comprises a scored region. **As to claim 29, Chiprich et al. teach a capsule which is brittle so that it can be broken using finger pressure (see col.2 lines 13-14). Also teach a breakable capsule with a single (see fig.2) or multiple (see fig.3) score line to provide a focal point for applying pressure to the capsule so that it may be readily broken for release of its contents (see col.4 lines 1-6). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the capsule of Ohki in order to provide a brittle capsule with score lines creating weakened portions to the capsule as taught by Chiprich for the purposes of creating a focal point at the weakened portion where a pressure would be applied to break and release the powder contents enclosed in the capsule.**

20. **As to claim 30, Ohki et al. do not disclose** a receptacle according to claim 27 wherein the weakened portion is opened when a blunt force is applied. **A close review of the applicant's disclosure reveals that the applicant has not established criticalities regarding a particular tip used with the opening member. Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to provide an opening member having either a blunt tip or an inclined cut needle tip as disclosed by Ohki where both tips are capable of perforating a capsule.**

21. **As to claim 31, Ohki et al. disclose** a receptacle according to claim 27 wherein the receptacle is a capsule **(see col.2 lines 30-31).**

22. **As to claim 32, Ohki et al. do not disclose** a receptacle according to claim 31 wherein the capsule comprises a wall comprising one or more of gelatin, hydroxypropyl methylcellulose, polyethyleneglycol-compounded hydroxypropyl methylcellulose, hydroxyproplycellulose, and agar. **As to claim 32, Chiprich et al. teach capsule wall composition of gelatin and cellulose/starch contents**

(see col.2 lines 55-68 and col.3 lines 1-18) providing a vehicle for dispensing pre-measured medicaments (see col.3 lines 29-30). Also teach the biodegradable nature of the gelatin capsule provides for consumer acceptance of disposable products. Since the capsules as taught by Chiprich contain a non-hygroscopic plasticizer, they require less moisture resistance in their packaging than traditional soft gelatin capsules and therefore provide cost efficiency because of less expensive packaging materials being required (see col.3 lines 38-45). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to add gelatin and cellulose contents to the wall of Ohki in view of Chiprich for the purposes of creating a medicine dispensing vehicle that requires less moisture resistance in their packaging than traditional soft gelatin capsules, therefore further providing cost efficiency because of less expensive packing materials.

23. **As to claim 33, Ohki et al. disclose** a receptacle according to claim 27 wherein the receptacle contains a powder pharmaceutical formulation **(see col.2 lines 30-31)**.

24. **As to claim 33, Ohki et al. do not disclose** a receptacle according to claim 33 wherein the powder pharmaceutical formulation comprises particles having a mass median diameter less than 10 gm. **A close review of the disclosure reveals that the applicant prefers a moisture content below about 10% by weight, usually below about 5% by weight, and preferably below about 3% by weight, also discloses such powder are described in the prior art (see specification page 18, lines 21-25). A range of moisture content (below 10%-below about 3%) presented by the applicant is recognized, however the applicant has not established criticalities between a moisture content of 10% or 3% by weight. As to claim 13, Chiprich et al. teach, a brittle gelatin capsule comprises about 5-15% water by weight. Therefore, it would have been obvious to one of ordinary skills in the art at the time the**

invention was made to modify the capsule of Ohki in view of Chiprich in order to provide a moisture content of 5-15% since it is well known in the art that a low water content is advantageously used in the process of making a powder-like medicine for the purposes of increasing the drying process of the powder.

Conclusion

25. The prior art made of record on form PTO-892 and not relied upon shows medicine dispensing device.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Shumaya B. Ali** whose telephone number is **571-272-6088**. The examiner can normally be reached on M-F 8:30 am-4: 30 pm.

27. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Henry Bennett** can be reached on **571-272-4791**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-6088.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shumaya Ali

Shumaya B Ali 4/25/2005
Examiner
Art Unit 3743

Henry Bennett
Supervisory Patent Examiner
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